

REMARKS

The Office Action dated November 29, 2003 presents the examination of claims 1-14. Claims 15-20 are withdrawn from consideration. Claims 1-12, 14, 16-17, and 20 are amended. Support for the recitation of "6 x SSC containing 0.5% SDS, 5 x Denhardt's, and 100 µg/ml salmon sperm DNA at 50°C" added to claim 1 is found on page 15, lines 16-21 of the specification. Support for amendments to claim 14 is found on page 23, lines 12-15 and 21-23, and on page 22, lines 17-21. Claim 21 is added. Support is found on page 22, line 7 to page 25, line 1 of the specification. No new matter is inserted into the application.

Request for Initialed Form PTO-1449

Applicants submitted Information Disclosure Statements on September 26, 2001 and August 12, 2002. The Examiner crossed out two references listed on the form PTO-1449 accompanying the IDS of September 26, 2001, and one reference listed on the form PTO-1449 accompanying the IDS of August 12, 2002.

With regard to the IDS of August 12, 2002, the Examiner apparently did not receive a copy of Spence et al., *Biochemistry and Cell Biology*, Vol. 64, No. 5, 1986. Although Spence et al. was cited in an International Search Report, which citations should have been forwarded from the International Bureau, Applicants

submit herewith a copy of Spence et al. for the Examiner's convenience.

With regard to the IDS of September 26, 2001, the Examiner crossed out the last two citations for apparently being improper. In response to the Examiner's remarks, Applicants resubmit herewith "T.E. Creighton, *The Amino Acid Sequence* (pages 31-42), in Proteins: Structures and Molecular Properties. W. H. Freeman and Company, New York, NY (2nd ed. 1993)." Applicants advise the Examiner that the last entry of the form PTO-1449 submitted on September 26, 2001 is a typographical error.

Applicants submit herewith a new form PTO-1449 listing these two references. The Examiner is respectfully requested to consider these references and initial and return the form PTO-1449 as evidence of his consideration.

Election/Restriction

The Examiner has required election in the present application between:

Group I, claims 1-14, drawn to a nucleic acid encoding ceramidase, vector and host cell comprising said nucleic acid, a recombinant method to make ceramidase;

Group II, claims 15, 18, and 19, drawn to antibodies and a method of use;

Group III, claims 16 and 17, drawn to a hybridization method to detect nucleic acid; and

Group IV, claim 20, drawn to a method of controlling the amount of ceramide in a cell or tissue.

For the purpose of examination of the present application, Applicants elect, with traverse, Group I, claims 1-14.

The Examiner notes that the claims of Groups III and IV represent a second and third use of the nucleic acid of the claims of Group I. Applicants respectfully request that the these claims (i.e., claims 16, 17, and 20) be rejoined once the examined claims are found to be patentable in accordance with the provisions of 37 C.F.R. § 1.104.

Objection to the Specification

The Examiner objects to the specification for the use of abbreviations. The Examiner particularly points out the recitations of "NBD ceramide" on page 9, and "GM1a" and "NMD" in Table 1, page 10, and requires that the specification be amended to recite the entire proper name of these terms.

In response to the Examiner's remarks, Applicants respectfully submit that the abbreviation "NBD" stands for "4-nitrobenz-2-oxa-1,3-diazole" as described in the attached **Exhibit 1** ("Molecular Probes," www.probes.com/servlets/product?item=1154). Thus, the

first recitations of "NBD" in the specification are amended as follows:

C12-NBD-fatty acid	12-(N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoyl acid
C12-NBD-ceramide	12-((N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoyl)sphingosine
NBD-N-Dodecanoyleosphingosine	12-((N-(7-nitrobenz-2-oxa-1,3-diazol-4-yl)amino)dodecanoyle)sphingosine
NBD-N-Hexanoylsphingosine	6-((N-(7-nitrobenz-2-oxa-1,3-diazole-4-yl)amino)hexanoyl)sphingosine

Regarding the term "GM1a," however, Applicants respectfully submit that this term is recommended by IUPAC-IUB as the proper name of a ganglioside molecular species. As evidence thereof, Applicants attach herewith **Exhibit 2** (M. A. Chester, *Eur. J. Biochem.* 257:293-298 (1998)), wherein "GM1a" is used in Table 3 (page 298). Since "GM1a" is a proper term well recognized by those of ordinary skill in the art, this term is not amended. Further, the Examiner is advised that there is no recitation of "NMD" in Table 1.

Finally, Applicants amend the recitation of "sulfatide (HS03-3Galb1-1'Cer)" on page 10, Table 1 to "sulfatide (HS03-3Galb1-1'Cer)." The third character should correctly be an alphabet "O" rather than 0 (zero) on the basis of support found in the marked

portion of the attached **Exhibit 3** (Dorland's Illustrated Medical Dictionary, 26 ed., W.B. Saunders Company, 1273 (1981)). Thus, this amendment does not constitute new matter.

Claim Amendments

The Examiner states that the claims are allegedly narrative and indefinite, and fail to conform with current U.S. practice. In response to the Examiner's remarks, the claims are amended into current U.S. practice form. Particularly, the phrase "of the sequence listing" is deleted from the claims.

Claim Objections

The Examiner objects to claims 2 and 10 for containing square brackets. The claims are amended in accordance with the Examiner's suggestions. Thus, the instant objection is overcome.

Rejection under 35 U.S.C. § 101

The Examiner rejects claims 1-3 and 8-14 for allegedly containing non-statutory subject matter. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

The claims are amended so that "gene" is replaced with "isolated nucleic acid" and "polypeptide" is replaced with "isolated polypeptide." Thus, the instant rejection is overcome.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 1-14 under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter not enabled by the specification. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner asserts that the specification enables a nucleic acid encoding SEQ ID NO:14 and SEQ ID NO:15, as well as nucleic acid sequences which hybridize thereto under stringent conditions recited on page 43 of the specification, but does not enable other sequences recited in the claims.

In order to overcome this rejection, the claims are amended to recite SEQ ID NOS: 14 and 15, hybridizing variant sequences, and degenerate sequences. Applicants respectfully submit that the claims, as amended, fully comply with 35 U.S.C. § 112, first paragraph. Withdrawal of the instant rejection is therefore respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 1-14 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Applicants respectfully submit that the claims, as amended, particularly point out and distinctly claim the subject matter which is the present invention such that the claims fully comply with 35 U.S.C. § 112, second paragraph. Withdrawal of the instant rejection is therefore respectfully requested.

Rejections under 35 U.S.C. § 102

"Commercially Known" Prior Art

The Examiner rejects claims 11 and 12 under 35 U.S.C. § 102(b) for allegedly being anticipated by "common knowledge" in the art. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner asserts that the recitation of "a part thereof" encompasses one nucleotide which is commercially available in the art. In order to overcome this rejection, the phrase "a part thereof" is deleted from the claims. Withdrawal of the instant rejection is therefore respectfully requested.

Okino '581

The Examiner also rejects claims 1, 2, 4-7, 9-11, and 14 under 35 U.S.C. § 102(e) for allegedly being anticipated by Okino '581 (U.S. Patent 6,258,581). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Okino '581 is directed to a ceramidase gene. Okino '581 fails to disclose SEQ ID NO: 14 or 15, or variant sequences which hybridize to a nucleotide sequence encoding SEQ ID NO: 14 or to SEQ ID NO: 15 under the stringent conditions recited in the claims. In order to overcome this rejection, former sections (C) and (D) of claim 1 are deleted.

Okino '581 fails to anticipate the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Koch et al.

The Examiner rejects claims 1, 4-7, 9, 11, and 14 under 35 U.S.C. § 102(b) for allegedly being anticipated by Koch et al. (*J. Biol. Chem.* 271:33110-33115 (1996)). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Koch et al. discloses a human ceramidase. Koch et al. fails to disclose SEQ ID NO: 14 or 15, or variant sequences which hybridize to a nucleotide sequence encoding SEQ ID NO: 14 or to SEQ ID NO: 15 under the stringent conditions recited in the claims. In order to overcome this rejection, former sections (C) and (D) of claim 1 are deleted.

Koch et al. fails to anticipate the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Marra et al.

The Examiner rejects claim 14 under 35 U.S.C. § 102(b) for allegedly being anticipated by Marra et al. (Database: EST, Accession Number AA920146). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Marra et al. teach an EST sequence of which 157 bases are identical to SEQ ID NO:15. Marra et al. fails to disclose an oligonucleotide probe or primer as recited in the amended claim 14. Specifically, Marra et al. fails to disclose an isolated oligonucleotide probe or primer which hybridizes under stringent conditions of 6 x SSC, containing 0.5% SDS, at a temperature of ((T_m of the oligonucleotide) -25°C) to the nucleic acid of claim 1,

or a complementary stand thereof, wherein said oligonucleotide probe or primer has a strand length of 15 to 40 bases.

Marra et al. fails to anticipate the present invention. Withdrawal of the instant rejection is therefore respectfully requested.

Conclusion

Applicants respectfully submit that the above remarks and/or amendments fully address and overcome and/or render moot the objections/rejections of record. The present application is in condition for allowance. The Examiner is respectfully requested to acknowledge patentability of at least claims 1-14.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

for M. Murphy Jr #28977
By _____
Marc S. Weiner #32,181
P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

Attachment(s) :

PTO-1449

Spence et al., *Biochemistry and Cell Biology*, Vol. 64, No. 5, 1986;
T.E. Creighton, *The Amino Acid Sequence* (pages 31-42), in *Proteins: Structures and Molecular Properties*. W. H. Freeman and Company, New York, NY (2nd ed. 1993);

Exhibit 1: Molecular Probes, www.probes.com/servlets/product?item=1154;

Exhibit 2: M. A. Chester, *Eur. J. Biochem.* 257:293-298 (1998);

Exhibit 3: Dorland's Illustrated Medical Dictionary, 26 ed., W.B. Saunders Company, 1273 (1981).